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MO EXAMINER

ART UNIT 623

PAPER NUMBER

11/09/98

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**08/942,369**

Applicant(s)  
**Chen et al**

Examiner  
**Marjorie Moran**

Group Art Unit  
**1623**



☒ Responsive to communication(s) filed on Oct 5, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-19 is/are pending in the application.

Of the above, claim(s) 1-11 and 19 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 12-18 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Election/Restriction***

Applicant's election with traverse of Group II, claims 12-18 in Paper No. 7 on 10/5/98 is acknowledged. The traversal is on the ground(s) that there is no serious burden on the examiner to search the claims of Group I as well as the claims of Group II. This is not found persuasive because the search required for Group I is not required for Group II. In addition, a search for either group would necessarily include a search of the nonpatent literature, thus a search for both groups would place an undue burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

An action on the merits of claims 12-18 follows.

### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

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The oath or declaration is defective because applicant has not given a post office address anywhere in the application papers as required by 37 CFR 1.33(a), which was in effect at the time of filing of the oath or declaration. A statement over applicant's signature providing a complete post office address is required.

### ***Specification***

The abstract of the disclosure is objected to because it contains no complete sentences. Appropriate correction is required. In addition, examiner recommends that the abstract and title be rewritten to describe the elected invention. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Regarding claim 12, there are no steps recited for detecting target microorganisms nor for determining the susceptibility of such microorganisms to antimicrobial agents, as set forth in the preamble of the claim. In the absence of such steps, the claim is indefinite.

Also regarding claim 12, lines 21-24 state that growth of organisms in a compartment comprising medium capable of sustaining growth of total microorganisms indicates the presence of bacteria. However, in lines 7-8 of the same claim, applicant recited use of a medium capable of growth of total microorganisms. This is supported by the specification on p. 11, lines 1-6, which recites that fungi may also be detected. As it is unclear whether growth of microorganisms in this compartment indicates the presence of only bacteria or of total microorganisms, as recited earlier in the claim, this claim is indefinite. This rejection may be overcome by inserting the words --or fungi-- after "bacteria" in line 24.

Claim 12 recites the limitation "that antimicrobial agent" in lines 30-31. There is insufficient antecedent basis for this limitation in the claim, therefore this claim is indefinite.

Claim 14 recites the limitation "the biological fluid" in line 1. There is insufficient antecedent basis for this limitation in the claim, therefore this claim is indefinite.

In addition, claim 14 recites "a chemical sample" or "an environmental sample", neither of which are biological fluids, or, necessarily, biological samples. As it is unclear whether the claim is intended to be limited to biological fluids, biological samples, or any sample which may contain microorganisms, this claim is indefinite.

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Claims 13 and 15-18 are indefinite because they depend from claim 12 and/or claim 14 and fail to rectify the indefiniteness of either claim 12 or 14.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over GIBSON *et al.* (C) in view of SANDERS (B).

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Applicant claims a method of simultaneously detecting target microorganisms in a biological sample and determining susceptibility of the microorganisms to antimicrobial agents wherein portions of a biological sample are separately added to compartments of an assay device which comprise, separately, a medium capable of sustaining growth of total microbial organisms, a medium capable of sustaining growth of target microbial organisms, and a susceptibility interpretation medium. Applicant further limits his method to detection of specific uropathogens in particular biological fluids.

GIBSON teaches a method for determining the susceptibility of microorganisms to antibiotics (col. 1, lines 13-15) and for detecting growth of target microorganisms (col.3, lines 2-6) wherein a sample is added to separate wells of a device, said wells containing medium capable of sustaining growth of a target microorganism or growth medium and antibiotic (susceptibility interpretation medium), the sample and medium in the device are incubated, and growth is detected and susceptibility determined (col. 3, line 42-col. 4, line 46). GIBSON also teaches that the microorganism detected in his method is *Eschericia coli*, primarily from fecal specimens (col. 4, lines 49-51). GIBSON does not teach medium capable of sustaining growth of total microbial organisms.

SANDERS teaches nutrient media capable of sustaining growth of a wide variety of microorganisms (col. 4, lines 12-34) for use in a method for determining the susceptibility of microorganisms to antibiotics (col. 1, lines 34-38).

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It would have been obvious to one of ordinary skill in the art at the time of invention to include the medium of SANDERS in the method of GIBSON where the motivation would have been to provide a positive control for microorganismal growth in the event that the selective media taught by GIBSON was incorrect for the microorganism present in the sample. For these reasons, claims 12-17 are obvious.

Claims 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over GIBSON *et al.* (C) in view of SANDERS (B) as applied to claims 12-17 above, and further in view of BROCCO (E).

Applicant claims a method of simultaneously detecting target microorganisms in a biological sample and determining susceptibility of the microorganisms to antimicrobial agents, as set forth above. Applicant further limits the antimicrobial agents to amoxicillin, clavulanic acid/amoxicillin, or enrofloxacin.

GIBSON in view of SANDERS make obvious a method of simultaneously detecting target microorganisms in a biological sample and determining susceptibility of the microorganisms to antimicrobial agents, as set forth above. They do not teach amoxicillin, clavulanic acid/amoxicillin, or enrofloxacin.

BROCCO teaches a method of determining susceptibility of uropathogens, specifically *Staphylococcus* and *Streptococcus*, to amoxicillin (p. 5, line 8-p. 6, line 7), and a clavulanic acid mixture (p. 9, line 4-p. 10, line 15).



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It would have been obvious to use the amoxicillin and clavulanic acid of BROCCO as antimicrobial agents in the method of GIBSON in view of SANDERS where the motivation would have been to test susceptibility of microorganisms to antibiotics commonly used to treat diseases caused by microorganisms in order to determine an appropriate course of treatment. For these reasons, claims 12-18 are obvious.

### ***Conclusion***

Claims 12-18 are rejected; claims 1-11 and 19 are withdrawn; and the specification is objected to.

The prior art made of record and not relied upon which is considered pertinent to applicant's disclosure is AVAKIAN (A), who teaches a method of determining sensitivity of microorganisms to drugs and HIMMLER *et al.* (D), who teaches use of enrofloxacin as an antibiotic.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached at (703) 308-4311. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Marjorie A. Moran  
Patent Examiner  
Art Unit 1623

*Kathleen K. Fonda*  
KATHLEEN K. FONDA  
PRIMARY EXAMINER

mm  
10/30/98